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Montgomery's legal and practical impact: A systematic review at 6 years

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Abstract

Rationale, Aims and Objectives: Six years ago, the Supreme Court judgement in *Montgomery v Lanarkshire* changed medical law. It introduced a new patient-based standard of care for the communication of treatment risks and alternatives, rejecting the doctor-based standard that had long governed all aspects of medical negligence. This is the first systematic review to analyse the literature on *Montgomery*. Our aim is to appraise and synthesize the literature on *Montgomery*'s impact on medicine and the law and to identify areas for further academic enquiry and implications for professional guidance and training.

Methods: Searches were run in Medline, Embase, PsycINFO, Web of Science, Scopus, Westlaw UK, HeinOnline, and LexisNexis. Two reviewers screened papers. Extracted data was analysed and discussed by an interdisciplinary team. PRISMA guidelines were followed.

Results: Of the 1134 papers identified, 100 met the inclusion criteria. These papers revealed significant disagreement on four core sets of issues, focusing on *Montgomery's* impact on: (1) legal and professional duties; (2) medical practice; (3) the patient experience; and (4) litigation. The first set addresses whether the case actually changed doctors' legal and professional duties, the relationship between GMC guidance and medical law, and the boundaries of *Montgomery*. The second explores whether the decision has incentivized defensive medicine, its resource implications, and doctors' knowledge of it. The third concerns whether and how the decision has promoted patient autonomy and involvement in their own care. The fourth focuses on whether the case has caused an increase in litigation.

Conclusions: Despite the abundance of legal and medical literature on *Montgomery*, many issues remain unresolved. Empirical research is required for many of the questions. Doctrinal analysis informed by medical knowledge is also required to assess whether *Montgomery* may have unrecognized ramifications—for example, whether it

will require the disclosure of risks associated with diagnostic uncertainty, where doctors advise patients without performing procedures.

KEYWORDS
consent, diagnosis, negligence, Montgomery, patient-centred care, systematic review

1 | INTRODUCTION

Six years ago, the Supreme Court's judgement in *Montgomery v Lanarkshire*[1] introduced a new patient-based standard of care for the disclosure of treatment risks and alternatives, rejecting the doctor-based *Bolam* standard that had long governed important aspects of medical negligence. The *Bolam* standard requires doctors to act 'in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art'.[2] Following *Montgomery*, doctors are now under a duty to 'take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments'.[1] A risk is deemed to be material if: (1) 'a reasonable person in the patient's position would be likely to attach significance to the risk'; or (2) 'the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it'.[1]

There is a substantial body of literature on the legal significance of the case and its practical significance for patients and doctors. This literature can be found in both legal and medical journals, but the two bodies of work rarely connect. This review systematically identifies, appraises, and synthesizes the literature on *Montgomery*. Bridging the current gap between legal and medical journals, it provides an analysis of how the two disciplines perceive *Montgomery*'s impact on the law, doctors, patients, and litigation. In addition, it identifies some issues that warrant further investigation.

2 | METHODS

A systematic review framework was employed to ensure a robust and replicable searching strategy. Critical interpretive synthesis was used to analyse the large body of literature from the medical and legal disciplines PRISMA guidelines were followed (see Data S1).

2.1 | Identification of studies

I.L.G. and I.K. developed the search strategy using an iterative process to answer the research questions. I.K. developed detailed searches for the medical databases; an adapted search was run in the legal databases to accommodate their structure.

For medical articles, searches were run in Medline via OVID, Embase via OVID, PsycINFO via Ebsco, Web of Science Core Collection, and Scopus. For legal articles, searches were run in Westlaw UK, Hein Online, and Lexis Nexis. The medical searches were run by I.K. on 26 March 2020 and re-run on 4 March 2021. The legal searches were run by I.L.G. on 7 April 2020 and re-run on 4 March 2021. See Data S2 for the search terms.

2.2 | Screening

Articles were screened to determine if they were original research articles, in English, and the title or abstract contained a discussion of *Montgomery v Lanarkshire* at any stage in its litigation.

2.3 | Study selection

For the medical literature, the titles and abstracts of the papers were screened by two members of the team (I.L.G. and A.S.) in Rayyan on 30 March 2020.

For the legal literature, which was difficult to export in a format suitable for Rayyan, the titles and abstracts were manually entered into an Excel spreadsheet and screened by two members of the team (I.L.G. and A.S.) on 14 April 2020.

2.4 | Inclusion criteria

Papers were included if they focussed on the *Montgomery* judgement and were peer reviewed.

2.5 | Exclusion criteria for data extraction

The following articles were excluded

1. Those that focused on *Montgomery's* application outside of medical practice (e.g., in banking, construction, midwifery, and pharmacy);
2. Those that only mentioned *Montgomery* briefly in the body of the text or in the footnotes;
3. Those focused on specific legal issues outside the law of negligence (e.g., the disclosure of confidential patient data; organ donation; and the non-delegable duties of hospitals);
4. Those with an anonymous author;
5. Abstracts, posters, replies to articles, book reviews, letters, and textbook chapters.

2.6 | Data extraction

ILG extracted data from the included papers.

3 | FINDINGS

Data was extracted from 100 papers (see Figure 1 for PRISMA flowchart).

Table 1 summarizes the themes that emerged from the literature.

The literature on *Montgomery* raises diverse issues. These can be usefully organized in four themes, namely the impact of *Montgomery* on: (a) legal and professional duties; (b) medical practice; (c) the patient experience; and (d) litigation.

3.1 | *Montgomery*'s impact on legal and professional duties

3.1.1 | Revolution or evolution?

A dominant claim in the literature on *Montgomery* is that it transformed the law of informed consent.[3-26] For example, one paper suggests that 'the *Montgomery* decision redefined the standard for informed consent and disclosure'.[7] Others make an even stronger claim, stating that 'the court enshrined the doctrine of informed consent formally into English law for the first time'.[25-30]

This account is challenged, however, by those who argue that the new *Montgomery* test 'is merely another step along the same

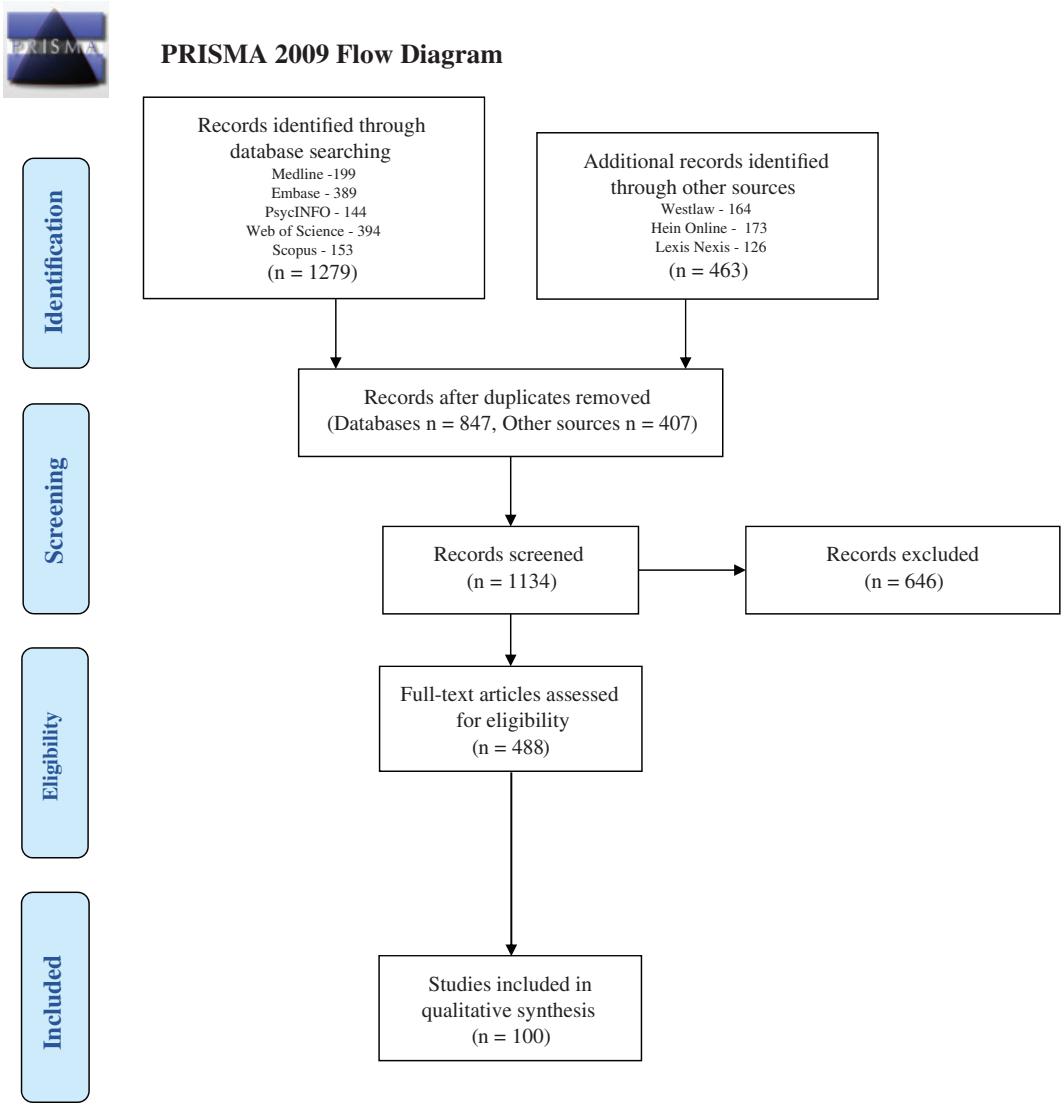

FIGURE 1 PRISMA 2009 flow diagram

TABLE 1 Referenced summary of themes which emerged from the literature

Themes	Articles	Examples
Montgomery and informed consent	3-37	3: 'the Supreme Court has clarified the law in relation to informed consent'. 9: 'the law of informed consent to medical treatment has recently been extensively overhauled in England'. 26: 'the case which has confirmed the safe delivery of the principle or doctrine of informed consent into the law'.
The extent of change in the legal standard	7,31-37	32: 'Rather than marking a significant shift in approach, the case confirms the general direction of travel, not only as a matter of law but also in terms of medical practice'.
Autonomy and paternalism	3,5-10,12-17,19,22,23,25-28,30-87	6: 'the decision promotes autonomy by requiring health professionals to provide the necessary information to give the patient the opportunity to make a decision reflecting best desire autonomy'. 7: 'The *Montgomery* case was framed as a clash of values - patient autonomy vs medical paternalism. In reality, medical decision making involves a nuanced negotiation of information'. 13: '*Montgomery*, in its determination to keep up with modern social standards of patient autonomy and consent, may have restricted paternalism to a harmful extent'. 47: 'paradoxically, its ruling supporting the principle of autonomy could be justified only by disregarding the individual patient's actual choices and characteristics in favour of a stereotype'.
What constitutes a material risk under *Montgomery*	9,11,19,21,23,32,33,45,46,60,74,76,86,88-91	32: 'there may be uncertainties as to what risks doctors should disclose as a matter of law…the advice is likely to be thus: if in doubt, disclose and explain it' 45: 'the term "material risks" remains ambiguous to both legal and medical professionals. Post- *Montgomery* cases have been wide-ranging in nature and have done little to provide definitional clarity to "material risks"'.
Montgomery's objective and subjective limbs	9,18,22,23,31,36,41,42,48,60,77,81,86,92	9: 'whilst it is correct to say that this limb of the test demonstrates sensitivity to a patient's values in its tailoring requirement, it does not, in our view, equate with giving primacy to the principle of respecting the patient's autonomy'. 31: 'what does "in the patient's position" mean? This is something that has been under-considered both in the literature and case law'. 41: 'the two limbs of the *Montgomery* test of materiality provide a framework for balancing the range of considerations the judgement requires should be taken into account in coming to a shared decision in a given case…the very need for two limbs, however, suggests that what is significant (and hence material) from the perspective of one limb may sometimes differ from what is significant (and hence material) from the other'.
What constitutes a reasonable alternative under *Montgomery*	9,18,25,28,31,42,59,60,77,92-94	25: 'reasonableness may be determined on an individual basis but in determining this inevitably evidence as to what would be a responsible body of professional practice would be relevant'. 93: 'what is meant by "reasonable" alternatives is far from clear, and so far, only sparse guidance has been provided by the courts'. 77: 'the requirement is limited to reasonable alternatives or variants, and the key lies in determining what amounts to reasonableness. The court however, provided absolutely no details on this, and while its inclusion only further advances the rights of the patient, the paucity of detail on what is required is not helpful'.
Bolam's role post-*Montgomery*	12,24,30-32,37,38,41,42,46,60,61,78,95-97	12: 'although *Bolam*'s dominance of informed consent has now been expressly laid to rest by the Supreme Court's decision's, its status in the wider corpus of healthcare law remains unclear'. 24: 'this case means that the *Bolam* test will no longer apply to the issue of consent…it will still be relevant to other aspects of care but was deemed unsuitable for cases regarding the discussion of risks with patients'. 32: 'While an express overruling of *Bolam* with regard to diagnosis and treatment is unlikely in the short to medium term, we may see attempts to limit the *Bolam* test further by qualification'. 38: '*Montgomery* has established that in one area of medical practice, *Bolam* shall no longer hold sway, and it is necessary to ask whether *Bolam* can survive much longer before it is banished from the issue of clinical negligence altogether. I believe that *Montgomery* will prove to be a turning point and that it spells the beginning of the end for the *Bolam* test in all its applications'.
The application of the therapeutic exception under *Montgomery*	5,6,22,25,31,33,34,37,58-60,78,82,92	5: 'the Therapeutic Exception has received much less attention, despite its seemingly incongruous place in a judgement that professes to adopt a patient-focused position intended to uphold autonomy rights'. 31: 'the precise boundaries placed on the therapeutic privilege are obscure and challenging to define, principally because it is difficult to identify any cases in which it has been successfully relied upon in this country'. 60: 'the therapeutic privilege of physicians to limit information in the interests of patients must not be jettisoned as it allows doctors to effectively heal they who desire to be healed'.

TABLE 1 (Continued)

Themes	Articles	Examples
Montgomery's application to cases concerning children	39,56	39 'In paediatric cases, *Montgomery* raises expectations that the law is currently ill-equipped to satisfy. Tort law provides a legal incentive to disclose relevant information to children but limits the availability of a remedy'. 56 'this study has illustrated the complexities of applying this statement to ICU. A paternalistic view, rather at odds with the *Montgomery* standard which clarifies that the UK informational standard is that determined by the patient, is still prevalent among P/NIC staff not least as there is no tradition of formal consent processes in this environment'.
Montgomery's application to health research/innovation matters	25,57	25: 'the Supreme Court judgement in *Montgomery* will clearly have a notable impact in relation to any future negligence case concerning failure to inform a research participant in a case where harm has resulted'. 57 'patient-centred analysis of reasonable disclosure based on materiality adopted in *Montgomery* and *Rogers* provides an appropriate and practical framework within which to evaluate disclosure obligations in the context of innovative treatment'.
Montgomery's impact on litigation levels	5,7,32,36,38,39,42,54,59,60,67,75,76,94,98	5: '*Montgomery* has potential to enhance the fear of litigation'. 94: 'some might expect the new rule to generate additional litigation though that might partly be off-set by a reduction in recriminations'.
The amendment of legal claims post-*Montgomery*	7,27,31,32,35,99	31: 'it is already clear that the ruling in *Montgomery* is having an impact and some statements of claim have evidently been amended in order to take account of the decision'.
The unpredictability of litigation post-*Montgomery*	5,32,36,42,47,60,64,76,100	5: 'the privilege has potential to result in an overly complicated legal approach …clinicians will find it harder to predict whether the Court will consider their decision not to disclose a risk unreasonable'. 42: 'it is true that the outcome of these types of cases will become less predictable'.
The role of professional medical guidance	3,4,7,8,17,19,20,25-27,29,31-34, 36,38-54,88-90,99,101	26: 'the fact that elements of the doctrine of informed consent have been promulgated for many years by the GMC with its partnership model of medical decision making means that doctors do not face a dramatic change in their approach to consent'.
Whether *Montgomery* will increase pressure on medical professionals	7,9,10,21,29,36,41,43,53,54,59,63-68,94,98,102	7: 'some doctors feared that more stringent disclosure requirements would risk overwhelming patients with information, causing distress or leading them to make poor decisions, while doctors' time would be taken up with lengthy explanations, creating a drain on healthcare resources'. 36: 'it is extremely unlikely *Montgomery* will manifest any practical impact'. 66: 'the fear that *Montgomery* would increase time pressures on doctors was seemingly borne out, with some reporting longer counselling times with patients'.
Whether *Montgomery* will incentivise defensive medicine	7,20,36,53,60-63,100	62: 'in a contractual, increasingly litigious culture, a culture wherein responsibility and blame must be privatized, doctors must lose interest in making judgements of any kind if they want to protect themselves'.
Montgomery's potential to improve medical practice	41,43,44,52,53,90,98,100	41: 'far from merely imposing on doctors a new legal duty to disclose, *Montgomery* marks a model of consent that in mirroring the realities of clinical decision making gives power to the clinical elbow in delivering best practice in contemporary person-centred care'. 43: '*Montgomery* far from adding to the pressures of practice becomes an ally to professionals and patients alike in seeking the resources needed to deliver best practice in contemporary clinical care'.
Medical education regarding informed consent	44,52,55,67,88	44: 'if *Montgomery* is to become a meaningful reality, medical students and clinicians at all levels and in all areas of practice must be supported and provided with the appropriate tools to enable them to strive to achieve this individualized patient-centred approach'.
Doctor's knowledge/awareness of the *Montgomery* judgement and compliance with it	10,11,49,53,55,56,66,67,90,102,103	10: 'Following the *Montgomery* ruling, we have demonstrated the current consent process in elective surgery is likely to be substandard, and may require additional steps to be taken by clinicians to ensure patients are fully informed to make decisions regarding their treatment'.
Disclosure of information regarding diagnosis	16,30,31,58-60	60: 'is it asking too much of patients to choose not only between potential treatments, but also diagnoses?'

trajectory through which [the law] has been travelling for some time' and that the case reflects an *evolution* rather than a *revolution*.[31] On this account, which also has significant support in the literature,[7,31-37] the case should be viewed as a 'tidying up of the law rather than a dramatic legal development'.[33]

3.1.2 | Symbolic or significant?

Even if *Montgomery* significantly changed the law, some argue that its impact on doctors' duties is at most symbolic because the General Medical Council (GMC) has long imposed a similar patient-oriented professional duty of risk disclosure.[4,7,8,17,19,20,25-27,29,31-34,36,38-54,88,89,99,101] The GMC's patient-centred duty was in fact highlighted by the Supreme Court in *Montgomery*, which cited passages from the GMC's 2008 and 2013 guidelines and noted that the 1998 guidelines that were in place at the time of Nadine Montgomery's pregnancy were 'broadly similar in effect' (although the lower courts may not have been aware of this).[1] The existence of GMC guidance is one reason that Lamb argues that the case has mostly 'symbolic' value,[36] but this account is challenged on three grounds in the literature.

The first challenge is based on the significant differences in the status and enforcement of legal and professional duties. For example, Adshead et al argue that 'in raising the status of shared decision making from guidance to legal requirement, *Montgomery* changes everything', as 'shared decision making is no longer optional but essential to valid consent'.[98] Healthcare providers can be held financially liable for a breach of *Montgomery*, which is not the case with the equivalent GMC duty. The GMC advises doctors to follow its guidelines, but deviations are not necessarily reprimanded. The GMC might take no action, give a warning, request undertakings or, for serious failings that impair a doctor's fitness to practice, refer a doctor to the Medical Practice Tribunal Service (MPTS). The MPTS has powers to restrict, suspend, or revoke a doctor's registration.[104] Given these differences in enforceability, many papers call for the GMC guidance to be updated post-*Montgomery*. As Devaney et al state, 'it is now critical that updated guidance is provided by the UK General Medical Council to give practitioners and service providers confidence that they are adhering to the law'.[93]

The second challenge to the claim that *Montgomery* is merely symbolic comes from authors who argue that the duties imposed by the GMC and the law are not actually the same.[3,55,98] For example, Arvind and McMahon argue that the law will have impacts that 'differ significantly from the GMC's goals', as they view *Montgomery* as presenting a consumerist and individualist version of the patient that is at odds with the partnership model that underpins the GMC guidance.[3] They highlight that we need to be aware of the 'challenge of transposing open-textured norms from one institutional context to a very different institutional context—law and medicine'.[3]

This third challenge is grounded in the claim that the content of legal and professional duties should not be the same, so that it is problematic if they now are. For example, Heywood and Miola argue:

> [M]edical law and the GMC guidance enjoyed what we considered to be a fruitful and well-structured relationship. This was because there existed a clear difference between the two standards. The law imposed a minimum standard that patients would be entitled to: any failure to achieve this standard would result in legal sanctions…Meanwhile, the medical profession aspired to more.[31]

On this account, *Montgomery* is not merely symbolic because it alters the relationship between professional and legal duties.

3.1.3 | Catching up or driving change?

The debate about whether *Montgomery* is merely symbolic raises questions about how the law and GMC guidance have shaped each other. On one account, the evolution of the law has been driven by the evolution of the medical practice. According to Purshouse and Cave, for example, 'in *Montgomery*, the law finally caught up with professional guidance'.[39] But this narrative is questioned by others. For example, O'Brien argues that the GMC guidance was actually shaped by legal cases questioning *Bolam* from the mid-1990s. He argues that when the 2008 GMC guidance 'explicitly called for a patient-centred approach', it was 'reflecting the process of departure from *Bolam* started by *Chester v Afshar* and *Pearce*'.[55] In his view, it is *clinical practice* that has been slow to catch up with legal paradigm shifts on risk disclosure and patient consent. *Montgomery* is therefore significant because '[t]he outright rejection of *Bolam* in *Montgomery* mandates that clinical practice does not continue to lag behind'.[55]

3.1.4 | Future extensions

The potential legal reach of *Montgomery*, beyond the factual contours of the case, receives significant attention in the literature. For example, *Montgomery*'s application in cases involving children is explored in both legal and medical papers,[39,56] and its application to health research and innovative treatment is explored in a small number of papers.[25,57] Citing two judicial decisions post-*Montgomery*,[105,106] one paper comments that the courts are applying *Montgomery* to the disclosure of information about 'post-treatment risks' and 'follow-up managements'.[22]

The potential application of *Montgomery* beyond treatment -- for example, to diagnosis -- continues to emerge in the literature. Most of these articles[16,30,31,58-60] focus on a Singaporean case, *Hii Chii Kok*,[107] where the court drew on *Montgomery* in ruling that material information includes information about the diagnosis. However, a few authors focus on UK law, such as Heywood and Miola who argue:

> If the law relating to information disclosure is about allowing patients to make their own decisions based on

> all of the relevant information—as *Montgomery* provides—then surely a potential alternative diagnosis, the existence of which may affect the patient's decision, would be information relevant to the patient's ability to make the choice that she wants to make.[31]

The possibility of extending *Montgomery* even further is explored in several papers, which suggest that *Montgomery*'s rejection of the deferential stance of *Bolam* may lead to a more general rejection of *Bolam*.[12,31,32,38,42,60,61,95-97] For example, Badenoch comments that 'it is necessary to ask whether *Bolam* can survive much longer before it is banished from the issue of clinical negligence altogether'.[38]

3.2 | *Montgomery*'s impact on doctors

The literature explores several ways in which *Montgomery* could impact medical practice.

3.2.1 | Encouraging defensive medicine

One widely discussed possibility is that *Montgomery* could encourage defensive medical practices. This concern was noted and rejected by the Supreme Court in its decision,[1] but Case argues that the Court 'gave short shrift to arguments based on the risk of defensive practice',[100] and many others share her concern.[7,20,36,53,60-63] For example, as Murphy comments, *Montgomery* could cause doctors to become 'less concerned with genuine understanding and consent from the patient and more concerned with mitigating the opportunities for litigation'.[60] It is unclear whether this is actually happening, however, as our systematic literature review revealed no empirical studies on this issue.

3.2.2 | Additional pressures on doctors

Another possibility, discussed in many papers, is that the disclosure requirements in *Montgomery* will create taxing burdens for doctors.[7,21,29,43,53,54,59,63-68,94,98,102] For example, Choudry et al comment that it creates 'extra demands on clinical appointments that will be difficult to meet at a time of constrained resources',[59] and there is some empirical evidence that doctors share this concern.[10,44,66] For example, a study by Harrison et al found that some doctors were 'reporting longer counselling times with patients',[66] and a study by Knight et al found that half of the respondents 'considered the allocation of further resources, particularly time, for the consent process…a current barrier'.[10] Laing argues that such burdens could worsen the low levels of professional morale and high levels of stress in the NHS workforce.[44]

In response to this concern, many papers question the premise that *Montgomery* actually creates new burdens, highlighting that the GMC has long imposed similar disclosure requirements.[4,7,8,17,19,20,25-27,29,31-34,36,38-54,88-90,99,101] For example, Lamb argues that 'it is unlikely that a slightly greater focus on the particular patient…will lead to any real practical impact on the day-to-day action of doctors'.[36] In fact, the Supreme Court made a similar point in *Montgomery*, noting the concern about time pressure but rejecting it on the grounds that the GMC had 'long required a broadly similar approach'.[1] The Court also noted that a similar legal requirement 'has long been operated in other jurisdictions, where healthcare practice presumably adjusted to its requirements'.[1]

However, the literature discussed above (in "Symbolic or significant?") identifies several reasons why the Supreme Court ruling may increase doctors' burdens despite similar duties in pre-existing GMC guidance. First, a breach of the duty can now result in financial liability. Second, the patient-oriented standard is now binding; there is no longer any ambiguity about whether this approach is merely advisable and aspirational. Third, the Court's approach may shift the doctor-patient relationship away from the partnership model and towards a consumeristic model of healthcare.

Some commentators accept, at least for the sake of argument, that *Montgomery* increases doctors' burdens, and argue that this is justifiable. For example, as Badenoch comments:

> [L]ack of time for adequate dialogue with the patient may seem an ever present and even insuperable problem. It must be overcome, because what is at issue is the patient's most basic and fundamental right to decide, on adequate information, whether to submit or not to proposed treatment, or which of alternatives to choose or accept.[38]

Others highlight that spending more time in discussion with the patient pre-treatment could save time and other resources down the line. For example, if the disclosure causes the patient to decline the treatment, this will save time spent in unwanted medical care[41]; or if they do accept the treatment, the disclosure might reduce 'the likelihood of doctors becoming the subject of a lawsuit'.[93] Birch and Todd calculated that the cost of spending 30 minutes extra with each patient (to ensure *Montgomery* compliance) for operations such as arthroplasty would be offset by reduced legal claims, leading to annual savings of £10 million.[54]

A final set of arguments in support of *Montgomery* identify ways in which it might improve medical practice.[41,43,44,52,53,98,100,103] For example, Herring et al conclude that the *Montgomery* standard 'gives power to the clinical elbow in delivering best practice in contemporary person-centred care'.[41] It also provides a legal justification for devoting the resources needed for good consent practices, as Adshead et al argue in their work on psychiatry: 'So long as shared decision making was optional there was no real incentive to provide the resources to support this'.[98] If the legal responsibilities are clearer, doctors may be better educated and supported in providing information to their patients.

3.2.3 | Doctors' awareness of and compliance with Montgomery

A common claim in the literature—particularly in the medical literature--is that *Montgomery*'s impact on medical practice

might be limited by doctors' limited awareness of the ruling.[10,11,49,53,55,56,66,67,69,102,103]

In empirical studies, the percentage of doctors who report familiarity with the ruling ranges from 8.3%[10] to 45%.[55] One study found that this varies across specialties (with 8.3% of orthopaedic surgeons reporting unfamiliarity with the ruling, compared to 18.8% of urologists and 20.2% of general surgeons), as well as clinician grade (with 80% of consultants reporting unfamiliarity, compared to 52% at the registrar or below).[10]

For these reasons, many conclude that we need to improve doctors' understanding of UK consent law.[44,52,55,67,88] Wheeler et al argue that 'this disparity between what is and what should be known dates from a long-term failure of medical education to teach clinical law'.[88] Laing emphasizes that 'if *Montgomery* is to become a meaningful reality, medical students and clinicians at all levels and in all areas of practice must be supported and provided with the appropriate tools to enable them to strive to achieve this individualised patient-centred approach'.[44] This systematic review found no papers about whether or how *Montgomery* has been incorporated into medical student training.

However, it might be a mistake to assume that increased knowledge of *Montgomery* will always result in a change in medical practice.[10,66,69] For instance, one study found that only half of the doctors who said they were aware of *Montgomery* (36.6% of the total sample) reported changing their practice as a result.[69] It is possible that the other doctors concluded that they were already compliant with *Montgomery's* requirements, but the paper does not address this issue.

3.3 | *Montgomery*'s impact on patients

3.3.1 | Patient-centred care and autonomy

It is widely agreed that *Montgomery* will foster more patient-oriented care, but there is a difference of opinion about what this means for patient autonomy.

Many articles focus on the Court's elevation of patient autonomy and its disapproval of medical paternalism.[3,5-10,12-17,19,22,25-28,30-68,70-86,90] The case is described as 'the final step in a legal power shift from paternalism to patient autonomy'[40] and 'a landmark case…which shifted focus from a traditional paternalistic model of consent towards a more patient-centred approach'.[33] However, others argue that this narrative is overly simplistic, with one paper noting that pitting autonomy and paternalism against one another does not adequately reflect how 'medical decision making involves a nuanced negotiation of information'.[7]

Other papers interrogate the ambiguity surrounding the concept of autonomy, including how the Supreme Court used the concept in *Montgomery*.[5,6,9,23,42] For example, Heywood highlights the Court's use of "autonomy" in *Montgomery* c"ompared to its use of "self-determination" in *Sidaway*:

> The variance in language may only be subtle, and it could be argued on one level that self-determination and autonomy mean the same thing, but the term autonomy somehow seems to evoke more powerful connotations of a rights-based approach from judges.[42]

Cave has a similar view and argues that the case showed a 'commitment to a more substantive concept of autonomy by the Supreme Court'.[6] However, other authors interpret the Court's view differently. For example, Arvind and McMahon argue that the Court adopted a consumerist version of autonomy, which they argue is problematic for the parties and more broadly for the 'development of medical law'.[3]

3.3.2 | Patients' views

We found only one empirical study of patients' views related to *Montgomery*.[21] Howard et al assess patients' views of material risk in the trauma setting, reporting that patients were unable to identify material risks following consent and that 'this highlights the difficulties of applying the *Montgomery* ruling in a trauma surgery setting'.[21]

3.4 | *Montgomery*'s impact on litigation

3.4.1 | Speculation on litigation trends

The possibility that *Montgomery* will lead to an increase in litigation is widely discussed in the literature. This possibility was in fact raised by the Supreme Court in *Montgomery*, which ultimately concluded that litigation might actually decrease:

> An approach which results in patients being aware that the outcome of treatment is uncertain and potentially dangerous, and in their taking responsibility for the ultimate choice to undergo that treatment, may be less likely to encourage recriminations.[1]

These comments by the Court were necessarily speculative, but the subsequent literature has also not reached any firm conclusions on this issue.[5,7,36,38,42,54,59,60,67,76,77,94,98] Some note that in the wake of *Montgomery*, lawyers amended claims that they had already submitted, adding an allegation of failure to obtain the patient's informed consent under the new rule.[7,27,31,32,35,99] Others suggest that a broader shift is unlikely given that doctors had a similar duty under GMC guidelines.[34,50,90] Discussing case law after *Montgomery*, Laing suggests that the floodgates fear 'has not necessarily' materialized.[44]

Surprisingly, six years after the judgement, there are no empirical analyses of overall litigation levels for information disclosure claims, although there is one specifically relating to children.[39] It reports, based on a freedom of information (FOI) application to NHS Resolution in March 2018, that 'paediatric claims related to non-disclosure of information have increased, whilst the number of successful claims has fallen'.[39] However, we note that the number of claims was too

small for statistical significance, and litigation rates for other types of medical negligence have also increased (which casts doubt on the idea that *Montgomery* is the sole or primary cause of the observed increase).

3.4.2 | Litigation outcomes less predictable

Even if litigation for negligent disclosure has not increased, many suggest that outcomes have become less predictable post-*Montgomery*.[5,32,36,42,47,60,64,77,100] This unpredictability is commonly attributed to uncertainty concerning how courts will assess material risks,[9,11,19,21,23,32,33,45,46,60,75,77,86,88,89,91,103] apply the subjective patient limb of the test,[9,18,22,23,31,36,41,42,48,60,81,86,90,92] allow the therapeutic exception,[5,6,22,25,31,33,34,37,58-60,78,82,92] and identify reasonable alternative treatments.[9,18,25,28,31,42,59,60,90,92-94] We found no data confirming or denying these assertions.

4 | DISCUSSION

This systematic review is the first to summarize and compare the legal and medical literature on *Montgomery*. Having demonstrated that its impact on medicine and the law is more complex and contested than it would seem, we now turn to three broader observations about the literature. First, the literature identifies a dynamic relationship between professional norms and the law. Second, many of the potential impacts of *Montgomery* are hard to verify due to a lack of empirical research. Third, the potential for *Montgomery* to apply beyond treatment requires further exploration.

4.1 | Relationship between GMC guidance and law

The review revealed a variety of views on the relationship between GMC ethical guidance and *Montgomery*. As discussed above, there is disagreement about whether *Montgomery* merely caught up with GMC guidance, whether the law should be as demanding as professional GMC guidance, and whether the GMC guidance itself had been shaped by the law. It is also worth noting that these arguments continue a debate about the interplay between GMC guidance and medical law that pre-dates *Montgomery*. For example, in 2010, Miola and Fovargue argued that the GMC's 2008 consent guidance embodied a 'step back' as 'doctors [were] required to tell their patients less than they were in 1998', bringing the ethical standard 'down and closer to the legal standard'.[108]

The particular cat-and-mouse dynamics of *Montgomery* and GMC guidance about information disclosure are interesting but in general, it is clear that law and professional guidance influence, but do not determine, each other. This has long been apparent, and a recent article by Samanta, Samanta, and Beswick[109] discusses the interplay between law and clinical guidelines (including those issued by the GMC and the National Institute for Health and Care Excellence) in detail. They note that although these guidelines are not dispositive in legal disputes, they 'can be persuasive or influential upon judicial decision making' and can affect 'decisions about whether to abandon or settle a claim at an early stage', as there is a presumption 'that clinicians should follow nationally endorsed and authoritative guidelines unless there are cogent reasons for not doing so'.[109] This can be problematic, however, if the guidelines were meant to be aspirational rather than binding.

At the same time, legal rules can influence clinical guidelines, given widespread acceptance that it is unethical and unprofessional for doctors to act unlawfully. In fact, *Montgomery* might have influenced GMC guidance, on this occasion causing it to raise the disclosure bar further. In its new consent guidance, released at the end of 2020,[110] the GMC advises that doctors should not only disclose alternative treatments, but also diagnostic uncertainty—an issue that we discuss below.

4.2 | A lack of empirical studies post-*Montgomery*

Although we identified a handful of empirical papers analysing doctors' and patients' reflections on *Montgomery* or the issues it raises, the extent of empirical research is very low considering the amount of empirical speculation in the literature. Further empirical research is needed to properly understand the impact of *Montgomery*.

For example, we found no empirical studies of whether the legal change in *Montgomery* has created new pressures on doctors, increased defensive medicine, or been incorporated into medical training or practice. Likewise, we found no studies of *Montgomery's* impact on litigation. NHS Resolution's responses to our FOI requests showed that payments where the primary claim was 'Fail To Warn-Informed Consent' increased by 177% between the years 2014/15 and 2019/20.[111] This data suggests that *Montgomery* may have led to increased litigation and/or damages, but further work is needed to determine this because the total number of medical negligence claims also increased and payments can be influenced by a small number of high value cases.

There is also very little empirical research about the impact of *Montgomery* for patients, although the case is widely considered 'a victory for patients'.[44] Further searches revealed a paper by Convie et al, which provides a qualitative synthesis of 16 studies that have explored patients' and physicians' views of informed consent.[112] While only six of these studies were from the United Kingdom, their conclusions could be relevant here. For example, they conclude that the desire of many patients 'to be seen as a "model patient" impairs their ability to actively participate in the informed consent process', as the patients feel 'a responsibility not to waste doctor's time with, what they thought was, their own trivial queries in relation to consent'.[112] Convie et al find that this is especially the case when 'patients [use] publicly funded and resource strapped healthcare'.[112] We found no other studies of UK patients' awareness of their rights under *Montgomery* or its impact on their medical decision making. Thus, the literature on this issue remains sparse despite Rob Heywood

et al highlighting the need for work on it in a 2008 study.[113] This gap in understanding is striking given the patient-centric emphasis of both *Montgomery* and the GMC guidance. Patients' experiences and views of their healthcare are also increasingly recognized as being critical to healthcare improvement research.[114,115]

Future empirical research could explore whether patients are familiar with their rights under *Montgomery*; which risks they consider material in particular settings; whether they value the communication that *Montgomery* requires; how they determine the risks they consider material; whether they perceive consent practices to be more defensive; and whether they desire information that is not currently assured (e.g., information about uncertainty in their diagnosis).

4.3 | *Montgomery*'s relevance beyond treatment

While the language of *Montgomery* focuses on treatment (requiring the disclosure of 'material risks involved in any recommended treatment' and 'any reasonable alternative or variant treatments'),[1] its rationale clearly extends further. For example, it seems uncontroversial to suggest that a doctor must disclose the material risks—as defined by *Montgomery*'s two-prong test—when seeking consent to a non-treatment medical procedure, such as a biopsy (although this has not, to our knowledge, been tested in court).

What is less clear is whether doctors should also disclose risks unrelated to medical procedures on the human body, such as those created by diagnostic uncertainty. This question has received little attention in the literature. This gap is problematic for three reasons. First, it leaves doctors uncertain about the scope of their duties of disclosure—and thus their potential liability. For example, it is unclear how much they should inform patients about their diagnoses, the diagnostic process, and the uncertainties inherent in this process. Second and relatedly, it leaves patients uncertain about the full extent of their rights. Third, the law is developing rules without sufficient attention to their boundaries and potential implications.

For these reasons, an interdisciplinary analysis of the potential application of *Montgomery* to all aspects of the medical encounter, including diagnosis, would be beneficial.

4.4 | Strengths and limitations

This is a comprehensive review of the literature on *Montgomery* reported in core medical and legal databases, analysed by an interdisciplinary team. Given the nature of this type of piece, we did not engage in direct analysis of the case law applying *Montgomery*, so our analysis will not capture cases that have not yet been discussed alongside *Montgomery* in the literature. In order to ensure a rigorous and replicable methodology, we did not include 'soft' literature such as blog posts; as a result, our review will only capture insights from the soft literature if they were subsequently published in academic papers. In order to refine the scope of the article, we excluded work that examined *Montgomery* outside of the medical context or that specifically addressed an area outside of medical negligence; by doing this, we may have missed some relevant analyses of situations analogous to those that occur in medicine. Papers written in other languages were not included. Finally, we note that the extraction of data for this review has more subjectivity than typical systematic reviews due to the nature of the literature being reviewed.

5 | CONCLUSIONS

This review identifies and reveals the limits of many common claims about the legal and medical significance of *Montgomery*. It is clear that the case significantly changed the law of informed consent—replacing a doctor-based standard for the disclosure of risk with a patient-based standard—but this change might be best seen as an evolution rather than a revolution.[31] Although some go further and argue that, in practice, *Montgomery* is primarily symbolic given that the GMC has long imposed a similar duty, this account fails to recognize important ways in which legal and professional duties differ. For example, the fact that the duty is now legally binding could increase time pressures on doctors or encourage defensive medicine. However, such criticisms are speculative, as there has been little empirical research in this area. Rather than making doctors work harder, *Montgomery* might actually be helping them, supplying a legal justification for the type of patient-centred care that they want to provide.

With respect to patients, most authors agree that *Montgomery* will foster more patient-oriented care, but there is a difference of opinion about what this means for patient autonomy—in part because there is disagreement about how autonomy is and should be conceptualized in the law. Very little is known about patients' views of the judgement, or whether *Montgomery*-compliant discussions are feasible in all settings. There is also a dearth of data about *Montgomery's* impact on litigation and speculations differ dramatically. There are reasons to believe that it will generate both more and less litigation, and that outcomes will be more unpredictable either way.

To resolve many of the questions generated by *Montgomery*, empirical research is required. For example, we must seek to understand patients' and clinicians' views on how the obligation to respect patients can best be met despite competing professional obligations and resource constraints. This research must be carefully configured to ensure that balanced data is collected from patients and clinicians, investigating the feasibility and opportunity costs of *Montgomery* alongside its direct and indirect benefits. There is also a need for further analysis of the case law following *Montgomery* to understand how the decision is being interpreted and applied by courts. For example, one question that requires attention is whether *Montgomery* governs disclosures of risks associated with diagnostic uncertainty, where doctors advise patients without performing procedures on their bodies. Thus, six years after *Montgomery*, there is still much empirical and legal research needed to understand its full significance.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTION

Zoë Fritz conceived the idea for the review. Isla Kuhn completed the medical systematic searches after discussion with Isabelle Le Gallez. Isabelle Le Gallez and Andrew Sagar screened the papers. Zoë Fritz, Isabelle Le Gallez, Kathleen Liddell and Jeffrey Skopek worked on the analysis and drafting of the paper. All authors reviewed and approved the final draft.

ETHICAL APPROVAL

No ethical approval required for this study.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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SUPPORTING INFORMATION

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